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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/760,307	01/11/01	MILSTEIN	S 1946/1A483-U

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EXAMINER

CHANNAVAIJALA, J.

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

06/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/760,307

Applicant(s)

MILSTEIN ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1-11-01.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-111 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Election/Restriction

I. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 38-49 and 75-86 are, drawn to method of delivery, classified in class 424, various subclasses.

II. Claims 13-37, 50-74 and 87-111 are, drawn to composition, classified in class 424, various subclasses.

II. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions composition and a method of delivery of the composition are different because the compositions of group II can be delivered by different routes such as intranasal, subcutaneous etc., as claimed by the applicants themselves.

III. This application contains claims directed to the following patentably distinct species of the claimed invention:

Group I. Method of delivery of the composition has the following patentably distinct species:

A. Subcutaneous - reads on claims 1-12, which claims the following patentably distinct species of perturbant:

1. Proteinoid- reads on claims 1-7

2. Acylated amino acid and acylated polyamino acid - reads on claim 8

3. Sulfonated amino acid and sulfonated polyamino acid - reads on claim 9

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4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid - reads on claim 10
5. Acylated ketone of amino acid and acylated ketone of polyamino acid - reads on claim 11
6. Carboxylic acid - reads on claim 12

B. Sublingual - reads on claims 38-49, which claims the following patentably distinct species of perturbant:

1. Proteinoid- reads on claims 38-44
2. Acylated amino acid and acylated polyamino acid - reads on claim 45
3. Sulfonated amino acid and sulfonated polyamino acid - reads on claim 46
4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid - reads on claim 47
5. Acylated ketone of amino acid and acylated ketone of polyamino acid - reads on claim 48
6. Carboxylic acid - reads on claim 49

C. Intranasal - reads on claims 75-86, which claims the following patentably distinct species of a perturbant:

1. Proteinoid- reads on claims 75-81
2. Acylated amino acid and acylated polyamino acid - reads on claim 82
3. Sulfonated amino acid and sulfonated polyamino acid - reads on claim 83
4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid - reads on claim 84
5. Acylated ketone of amino acid and acylated ketone of polyamino acid - reads on claim 85
6. Carboxylic acid - reads on claim 86.

Group II. Composition has the following patentably distinct species:

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A. Subcutaneous - reads on claims 13-37, which claims the following patentably distinct species of a perturbant:

1. Proteinoid- reads on claims 13-17, 23-26 and 32-37
2. Acylated amino acid and acylated polyamino acid - reads on claims 18 and 27
3. Sulfonated amino acid and sulfonated polyamino acid - reads on claims 19 and 28
4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid - reads on claims 20 and 29
5. Acylated ketone of amino acid and acylated ketone of polyamino acid - reads on claims 21 and 30
6. Carboxylic acid - reads on claims 22 and 31

B. Sublingual - reads on claims, 50-74 and 111, which claims the following patentably distinct species of a perturbant:

1. Proteinoid- reads on claims 50-54, 60-63, 67-4 and 111
2. Acylated amino acid and acylated polyamino acid - reads on claims 55 and 64
3. Sulfonated amino acid and sulfonated polyamino acid - reads on claims 56 and 65
4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid - reads on claims 57 and 66
5. Acylated ketone of amino acid and acylated ketone of polyamino acid - reads on claims 58 and 67
6. Carboxylic acid - reads on claims 59 and 68

C. Intranasal - reads on claims 75-86, which claims the following patentably distinct species of perturbant:

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1. Proteinoid- reads on claims 87-91, 97-100 and 106-110
2. Acylated amino acid and acylated polyamino acid - reads on claims 92 and 101
3. Sulfonated amino acid and sulfonated polyamino acid - reads on claims 93 and 102
4. Acylated aldehyde of amino acid and acylated aldehyde of polyamino acid - reads on claims 94 and 103
5. Acylated ketone of amino acid and acylated ketone of polyamino acid - reads on claims 95 and 104
6. Carboxylic acid - reads on claims 96 and 105.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Due to the complex nature of the restriction between groups and species, a written restriction requirement is hereby sent to the applicant.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

IV. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-7921 for regular communications and 703-308-7921 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi Channavajjala
June 26, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

